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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,197	03/12/2004	Don Fishbein	52427-AB/JPW/GJG	8168

7590

06/01/2005

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New York, NY 10036

EXAMINER
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LEWIS, AMY A

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/799,197	<b>Applicant(s)</b> FISHBEIN, DON	
	<b>Examiner</b> Amy A. Lewis	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>A-F</u> . | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1614

## DETAILED ACTION

### *Status of the Case*

The preliminary amendment to the specification, filed 12 March 2004, has been entered. Accordingly, the specification has been amended to include updated continuity data.

In the remarks, filed 12 March 2004, claims 3-15, and 17-29 were cancelled *without prejudice*. Claims 1, 2, and 16 are pending in the current application.

### *Double Patenting*

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

#### *Statutory Type Double Patenting:*

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 2, and 16 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 2, and 16 of copending Application No. US 2004/0235940 A1.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

#### *Obviousness Type Double Patenting:*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

Art Unit: 1614

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claims 1, 2, and 16 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 12 of U.S. Patent No. 6,576,659 B1.

Instant claims 1 and 2 are drawn to a method of treating/improving the rate of healing a wound in a patient comprising administering a therapeutically effective amount of oxandrolone. Conflicting claim 1 of U.S. Patent No. 6,576,659 B1 is drawn to the same method of treating a skin wound in a patient comprising administering oxandrolone. Claim 1 of the '659 patent specifies topical or oral administration of oxandrolone and that the wound be a burn, ulcer or skin graft. Since the same agent (oxandrolone) is being used to treat the same conditions (wounds), it would have been obvious to one of ordinary skill in the art that an increased rate of healing would have occurred in both cases.

Instant claim 16 is drawn to a method of treating burn-induced weight loss in a burn patient comprising administering a therapeutically effective amount of oxandrolone in conjunction with a protein supplement. Conflicting claim 12 of U.S. Patent No. 6,576,659 B1 is drawn to the same method, but includes oral or topical administration of the oxandrolone. It

Art Unit: 1614

would have been obvious to one of ordinary skill in the art to administer oxandrolone orally or topically motivated by ease of administration.

2) Claims 1, 2, and 16 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 12 of U.S. Patent No. 6,828,313 B2.

Instant claims 1 and 2 are drawn to a method of treating/improving the rate of healing a wound in a patient comprising administering a therapeutically effective amount of oxandrolone. Conflicting claim 1 of U.S. Patent No. 6,828,313 B2 is drawn to the same method of increasing the rate of healing of a skin wound in a patient comprising administering oxandrolone. Since the same method and agent is being used to treat the same condition, it would have been obvious to one of ordinary skill in the art that an improved rate of healing would have occurred in both cases.

Instant claim 16 is drawn to a method of treating burn-induced weight loss in a burn patient comprising administering a therapeutically effective amount of oxandrolone in conjunction with a protein supplement. Conflicting claim 18 of U.S. Patent No. 6,828,313 B2 is drawn to the same method of administering oxandrolone, however it does not include administration of a protein supplement. It is self-evident to administer protein supplements to aid weight gain (i.e. to restore lean body mass); indeed a normal diet contains "protein supplements." It would have been obvious, therefore, to have administered protein supplements to recovering burn patients in the instant claim motivated by the desire to improve weight gain and to aid their recovery.

Art Unit: 1614

***Pertinent Art:***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Demling, R.H. "Oxandrolone, an anabolic steroid, enhances the healing of a cutaneous wound in the rat." *Wound Repair and Regeneration* (March-April 2000): pages 97-102.
- Demling, R.H. "Comparison of the anabolic effects and complications of human growth hormone and the testosterone analog, oxandrolone, after severe burn injury." (1999) *Burns* 25: pages 215-221.
- Demling, R.H. and DeSanti, Leslie. "Oxandrolone, an anabolic steroid, significantly increases the rate of weight gain in the recovery phase after major burns." (1997) *The Journal of Trauma: Injury, Infection, and Critical Care* 43(1): pages 47-51.
- Demling, R.H. "Use of anticatabolic agents for burns." (1996) *Current Opinions in Critical Care, Vol. 2*: 482-491.

Regarding the Demling article "Use of anticatabolic agents for burns" (1996) *Current Opinions in Critical Care, Vol. 2*: 482-491, it was established in the parent case Application No. 10/011,377 (now U.S. Pat. 6,828,313) that this was unavailable as prior art, and is therefore unavailable as prior art in the instant application, which has the same priority date. See "Remarks" filed on 22 September 2003 in Application No. 10/011,377.

Art Unit: 1614

Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is (571) 272-2765. The examiner can normally be reached on Monday-Friday, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy A. Lewis  
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